EXHIBIT G

LEXSEE 2005 US APP LEXIS 1709

ISCO INTERNATIONAL, INC., Plaintiff-Appellant, v. CONDUCTUS, INC., and SUPERCONDUCTOR TECHNOLOGIES, INC., Defendants-Cross-Appellants.

04-1007, 04-1008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

123 Fed. Appx. 974; 2005 U.S. App. LEXIS 1709

February 3, 2005, Decided

NOTICE: [**1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

PRIOR HISTORY: *ISCO Int'l, Inc. v. Conductus, Inc., 279 F. Supp. 2d 489, 2003 U.S. Dist. LEXIS 14939 (D. Del., 2003)*

DISPOSITION: Affirmed.

COUNSEL: For CONDUCTUS, INC., Defendant-Cross Appellant (04-1007): PRINCIPAL ATTORNEY, GOODWIN, LAWRENCE B., Chadbourne, & Parke, New York, NY; OF COUNSEL ATTORNEY, HORWITZ, RICHARD L., Potter Anderson, Wilmington, DE; OF COUNSEL ATTORNEY, HOPKINS, DENNIS C., Chadbourne & Parke, New York, NY; OF COUNSEL ATTORNEY, BASOV, DANIEL, Chadbourne, & Parke, New York, NY.

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For SUPERCONDUCTOR TECHNOLOGIES, INC., Defendant-Cross Appellant (04-1007); PRINCIPAL [**2] ATTORNEY, PLIMACK, MICHAEL K., Heller Ehrman, San Francisco, CA; OF COUNSEL ATTORNEY, PARSONS, JR., DONALD F., Morris, Nichols, Wilmington, DE; OF COUNSEL ATTORNEY, BRAINERD, ALEXANDER L., Heller Ehrman, Menlo Park, CA; OF COUNSEL ATTORNEY, HARTH, DAVID J., Heller Ehrman, San Francisco, CA; OF COUNSEL ATTORNEY, MAMMEN, CHRISTIAN E., Heller Ehrman, San Francisco, CA.

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For SUPERCONDUCTOR TECHNOLOGIES, INC., Defendant-Cross Appellant (04-1008): PRINCIPAL ATTORNEY, PARSONS, JR., DONALD F., Morris, Nichols, Wilmington, DE.

JUDGES: Before LOURIE, Circuit Judge, ARCHER, Senior Circuit Judge, and PROST, Circuit Judge.

OPINION BY: [*975] LOURIE

OPINION: LOURIE, Circuit Judge.

ISCO International, Inc. ("ISCO") appeals from the decision of the United States District Court for the

District of Delaware: (1) denying its motion for judgment as a matter of law ("JMOL"), thereby sustaining a jury verdict in favor of Conductus, [**3] Inc. and Superconductor Technologies, Inc. (collectively, "the defendants") holding the asserted claims of ISCO's United States Patent *6,263,215* to be invalid and not infringed; and (2) adopting the jury's advisory determination that the *'215* patent is unenforceable due to inequitable conduct. *ISCO Int'l, Inc. v. Conductus, Inc., 279 F. Supp. 2d 489 (D. Del. 2003)* ("Decision on Appeal"). The defendants cross-appeal from the decision granting ISCO's motion for JMOL that it did not engage in unfair competition. Id. We affirm.

BACKGROUND

ISCO sued the defendants for allegedly infringing its *'215* patent, which is directed to a receiver front end for a cellular base station. At controversy are claim limitations pertaining to a set of cryogenically-cooled components--RF filters made from high-temperature superconducting material, and low-noise amplifiers--coupled to an automatic bypass circuit for routing signals around those components in the event of a cooling failure. Claim 10, the only claim at issue on appeal, reads as follows:

> A receiver front end for receiving wireless signals on a plurality of channels, the receiver front end comprising:
>
> [**4]
>
> a plurality of planar filters for filtering a corresponding plurality of RF signals corresponding to a plurality of channels to form a corresponding plurality of filtered RF signals;
>
> a corresponding plurality of amplifiers for amplifying the plurality of filtered RF signals;
>
> a cryogenic cooler for cryogenically cooling the plurality of filters and amplifiers, the cryogenic cooler having a cooling member being configured to cool simultaneously the plurality of planar filters and the plurality of Tplanar amplifiers; and
>
> [*976] a switched bypass circuit around the receiver front end and one or more sensors, wherein in a first mode when the one or more sensors measure acceptable operational parameters the bypass circuit is unswitched such that RF signals pass through the plurality of filters and amplifiers in the cryogenic cooler and not through the bypass circuit and in a second mode when the one or more sensors measure at least one unacceptable operational parameter the bypass circuit is switched and RF signals pass through the bypass circuit and not through the plurality of filters and amplifiers in the cryogenic cooler.

'215 patent, col. 20, ll. 41-65 (emphases [**5] added).

The case was tried to a jury, which returned a verdict in favor of the defendants; the asserted claims were found to be invalid for obviousness, not infringed, and unenforceable for inequitable conduct. The jury also found in favor of the defendants on their counterclaim that ISCO engaged in unfair competition. Arguing that the verdict was not supported by substantial evidence, ISCO moved for JMOL and for a new trial. The district court granted ISCO's motion for JMOL only on the unfair competition claim, but sustained the verdict of invalidity and noninfringement, and adopted the jury's advisory conclusion of unenforceability for inequitable conduct. Notwithstanding the inequitable conduct determination, the district court did not find the case exceptional, and accordingly denied the defendants' motion for attorney fees under *35 U.S.C. § 285*.

On appeal, ISCO challenges the district court's denial of JMOL on the issues of invalidity, noninfringement, and unenforceability, while the defendants cross-appeal from the ruling granting JMOL in overturning the jury's verdict on unfair competition. The denial of attorney fees is not being appealed. We have jurisdiction [**6] pursuant to *28 U.S.C. § 1295(a)(1)*.

DISCUSSION

On appeal from a judgment denying a motion for JMOL following a jury trial, an appellant "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that

the legal conclusion(s) implied from the jury's verdict cannot in law be supported by those findings." *Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)*. Accordingly, fact findings reviewed under the substantial evidence standard require affirmance unless it can be shown that no reasonable juror could have reached such a result. See id. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938)*. Given the highly deferential nature of the substantial evidence standard and because the issues are "highly fact-specific and evidence-oriented," this case provides yet another illustration of "the difficulty appellants face in attempting to persuade a court to reverse a jury verdict involving questions of fact." *In re Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1532 (Fed. Cir. 1992)*. [**7]

A. Invalidity

ISCO attacks the verdict of invalidity primarily on two grounds: (1) that the jury was not entitled to consider the ARPA report n1 as prior art; and (2) that the jury could not have reasonably reached its conclusion of obviousness based on the [*977] evidence presented at trial. We address each of these contentions in turn.

> n1 Advanced Research Projects Agency ("ARPA"), "HTSC Dual Use Applications Survey-Final Report: HTS Filter Applications: Cellular Telephone Base Station Equipment," presented Feb. 7, 1995. (J. A. 5142-5235).

1. The ARPA Report as Prior Art

As a threshold matter, ISCO accuses the district court of having erred in denying its motion for JMOL by allegedly imposing on ISCO the burden of proving that the ARPA report was not prior art. While unfortunate, any mischaracterization of the burden of proof in an opinion, by itself, does not warrant reversal. See *Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540 (Fed. Cir. 1983)* ("We sit to review judgments, [**8] not opinions."). "[I] f the district court failed to properly place the burden of proof, this court will do so." *Union Carbide Corp. v. Am. Can Co., 724 F.2d 1567, 1573 (Fed. Cir. 1984)*. In order to prevail, the appellant must therefore show that "the result, as opposed to the reasoning, is erroneous as a matter of law." *Id. at 1573-74*.

Claiming a conception date no later than December 1994, ISCO insists that the ARPA report, which was first publicly presented in February 1995, was not prior art. In support of this contention, ISCO refers to various drafts of a December 1994 proposal, entitled "Cryo-REACH TM Base Station Prototype," that were prepared by ISCO's predecessor and which allegedly disclosed the device of claim 10.

We agree with the trial court that the ARPA report was prior art because the December 1994 drafts did not evidence a conception of the claimed invention. "Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986)* [**9] (internal quotation marks omitted) (emphases added). The record reflects that ISCO's predecessor did not have a "definite and permanent idea" of the "complete" invention defined in claim 10 at a time antedating the ARPA report. Specifically, the December 1994 drafts indicate that ISCO's predecessor did not recognize or appreciate the automatic bypass circuit as being part of the invention then conceived. "It is well-settled that conception ...cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention represented by the [claims]." *Breen v. Henshaw, 472 F.2d 1398, 1401 (CCPA 1973)*. Because ISCO's predecessor failed to appreciate certain inventive features at the time of the alleged conception, ISCO cannot rely on a later recognition of those features to retroactively cure an incomplete conception.

That ISCO's contentions effectively amount to an argument for nunc pro tunc conception is apparent upon reviewing a December 14, 1994 draft marked "Plaintiff Trial Exhibit: PTX-362" (J. A. 1725-1729), which declares:

The REACH TM receiver proposed herein is unique in that it involves:

> (1) fully [**10] integrated thin film superconducting components,

> (2) ferroelectrically-tuned filter and receiver components,
> (3) integrated, GaAs cryo-amplifiers,
> (4) low noise oscillator, mixer, downconverter,
> (5) frequency-hopping capability, and
> (6) compact cryo-packaging.

PTX-362 at 3 (J. A. 1726) (emphases added). Whereas the filters, amplifiers, and cryogenic cooler required by claim 10 are duly listed as "unique" features, the automatic bypass circuit is conspicuously absent. Rather, that feature is listed elsewhere:

> The [Technology Reinvestment Program] proposal will be to build and test the 2 GHz "cold front end" components, [*978] integrate the components into complete sub-system [sic], add lightning protection and automatic bypass circuitry as needed to meet PCS service provider requirements, perform the system integration, address manufacturing issues, and design system control hardware/software.

Id. at 4 (J. A. 1727) (emphasis added). Here, the drafter of the proposal apparently did not view the automatic bypass circuit to be an essential component, as it was to be added only "as needed," just like "lightning protection." The lack [**11] of appreciation for the bypass feature as an inventive element is further revealed where, in a list of "product engineering issues" to be resolved, the entry specifically describing the bypass--i. e., "(5) bypass circuitry that automatically routes signal flow around the REACH TM receiver if either the electronics or the compressor fails"--is crossed out in its entirety and is replaced with an entry for "24 V power supply circuitry" in subsequent drafts, such as the one dated December 19, 1994 marked "Plaintiff Trial Exhibit: PTX-299." Compare PTX-362 at 4-5 (J. A. 1727-28) with PTX-299 at 10-11 (J. A. 1542-43). Given that the most detailed--albeit short--description of the automatic bypass circuit could not survive an editorial revision, that feature can hardly be considered part of a "definite and permanent" conception of the invention of claim 10.

In subsequent drafts of the December 1994 proposal, the most substantive description of the automatic bypass circuit that remains is the previously-noted cursory mention that a bypass can be added "as needed," but that provides an insufficient basis for extrapolating therefrom the detailed limitations in claim 10 pertaining [**12] to the specific operational modes of the bypass, its sensors, and the signal path. See *Singh v. Brake, 317 F.3d 1334, 1340, 48 Fed. Appx. 766 (Fed. Cir. 2002)* ("A conception must encompass all limitations of the claimed invention ...").

In short, the deletion of details pertaining to, and the cursory mention of, the automatic bypass circuit in the draft proposals are inconsistent with the argument that the conception to be proven by those drafts included that element as an inventive feature. Substantial evidence thus supports the jury's implicit finding, see *Perkin-Elmer Corp., 732 F.2d at 893* (noting that "the law presumes the existence of findings necessary to support the verdict the jury reached"), that the December 1994 draft proposals fail to establish the conception date for claim 10, such that the ARPA report was prior art.

2. Obviousness

Even if the ARPA report was prior art, ISCO contends that it is not an invalidating reference that could have supported the jury's finding of obviousness because the record allegedly lacks evidence of a motivation to modify its teachings to obtain the device of claim 10. For similar reasons, ISCO disputes the evidentiary [**13] significance of another prior art reference presented at trial, the Robertson article, n2 which it deems tobe non-analogous art that was not entitled to consideration by the jury in its obviousness inquiry. We disagree; the record shows that the jury could have reasonably considered these references to be invalidating prior art.

> n2 Mark A. Robertson, "Two applications of HTS technology on an airborne platform," in Proceedings of the International Society for Optical Engineering (SPIE): High-Tc Microwave Superconductors and Applications, Jan. 1994. (J. A. 5257-5264).

Regarding the alleged deficiencies of the ARPA report, ISCO insists that it does not suggest the use of cryogenically-cooled amplifiers as required by claim 10, [*979] and that it fails to teach the use of an automatic bypass circuit. However, the suggestion or motivation to

modify a reference may be derived from the knowledge of those skilled in the art or from the nature of the problem to be solved. See *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996).* [**14] Considerable evidence was presented at trial of the knowledge of a skilled artisan in the relevant art and the nature of the problem, from which the jury could have reasonably discerned a motivation to modify the ARPA report to obtain the invention of claim 10.

Specifically, the jury was presented with prior art references showing that cooled amplifiers, automatic bypass circuitry, and their benefits were well-known in the art at the time of invention--e. g., the Robertson article mentions the noise-reducing effect of using cryogenically-cooled amplifiers. (J. A. 5257). The jury also heard testimony from at least two expert witnesses who explained how a skilled artisan reading the ARPA report would have found it obvious to modify its teachings to include cooled amplifiers and an automatic bypass. The ARPA report itself focuses on the problem of cryocooler reliability and suggests a switchable bypass as a possible solution. (J. A. 5232). Given the knowledge in the art presented at trial and the nature of the problem to be solved as articulated in the ARPA report, the jury's conclusion that claim 10 would have been obvious in view of the modified teachings of the ARPA report was [**15] supported by substantial evidence.

Turning to the Robertson article, ISCO argues that it is non-analogous art because it is directed to military--not cellular--applications. We find this basis for disqualifying the Robertson article to be without merit in view of the fact that the December 1994 draft proposals, on which ISCO has attempted to establish a conception date for claim 10, are directed to a project for developing "front end hardware for application to civilian wireless communications and military EW and mobile communications systems." See, e. g., PTX-299 at 1 (J. A. 1533) (emphases added). As for its role in the obviousness inquiry, the Robertson article teaches all the key limitations of the device of claim 10: the simultaneous cooling of filters and amplifiers, and the addition of a bypass relay to safeguard the system in the event of a cooling failure. While ISCO disputes whether the bypass relay disclosed in the Robertson article is necessarily automatic in operation, the jury could have reasonably concluded, based on the context provided by the evidence presented at trial of the knowledge in the art, that the Robertson article would have rendered claim 10 [**16] obvious, either alone or in combination with the ARPA report.

In sum, our review of the record under the substantial evidence standard accorded to the jury's conclusions provides us with no grounds for disturbing the verdict of invalidity.

B. Other Issues

Because we are affirming the judgment of invalidity, the issue of infringement has been rendered moot. *Lough v. Brunswick Corp., 86 F.3d 1113, 1123 (Fed. Cir. 1996)* ("No further public interest is served by our resolving an infringement question after a determination that the patent is invalid."). Nor do we reach the inequitable conduct issue in light of the district court's denial of the defendants' request for attorney fees. Cf. *Buildex, Inc. v. Kason Industries, Inc., 849 F.2d 1461, 1466 (Fed. Cir. 1988)* (remanding case, after holding patent invalid, in order to allow district court to decide whether case is exceptional for purpose of fee award). As the effect of unenforceability [*980] on a patent held invalid is only meaningful as a basis for the award of attorney fees, the denial of which is not herein appealed, the issue is moot.

As for the defendants' cross-appeal, we affirm the district [**17] court's grant of JMOL on the unfair competition claim for reasons set forth in its detailed opinion, in particular, that the defendants did not prove bad faith in the enforcement of the patent. Moreover, ISCO, as a later assignee of the patent, was not a party to the alleged inequitable conduct.

We have considered the parties' other arguments and conclude that they are either unpersuasive or unnecessary for resolution of this appeal.

CONCLUSION

For the foregoing reasons, we conclude that the district court did not reversibly err, and accordingly affirm.

LEXSEE 1998 US DIST LEXIS 19555

IN RE WARFARIN SODIUM ANTITRUST LITIGATION

C.A. No. MDL 98-1232-SLR, (98 Civ. 1695) (S.D.N.Y.), (97-659) (D. Del.), (97-670) (D. Del.), (98-178) (S.D. Fla.), (98-697) (W.D. Pa.)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

1998 U.S. Dist. LEXIS 19555; 1999-1 Trade Cas. (CCH) P72,457

December 7, 1998, Decided

NOTICE: [*1] FOR ELECTRONIC PUBLICATION ONLY

DISPOSITION: Defendant's motion to dismiss plaintiff's claims granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims granted.

COUNSEL: For Barr Laboratories, Inc., Plaintiff: Kevin G. Abrams, Esquire, Richards Layton & Finger, Wilmington, Delaware.

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For Kusnerik, Altman, Class Plaintiffs: Bernard Persky, Esquire, Barbara J. Hart, Esquire, Of Counsel, Goodkind, Labaton, Rudoff & Sucharow LLP, New York, New York.

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For Defendants: Thomas C. Morrison, Esquire, Frederick C. Warder, III, Esquire, Patterson, Belknap, Webb & Tyler, New York, New York.

For Defendants: Philip S. Beck, Esquire, Adam Hoeflich, Esquire, Bartlit, Beck, Herman, Palenchar & Scott, Chicago, Illinois.

JUDGES: Sue L. Robinson, District Judge.

OPINION BY: Sue L. Robinson

OPINION:

MEMORANDUM OPINION

Dated: December 7, 1998
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This litigation consists of five actions consolidated here by the Judicial Panel on Multidistrict Litigation pursuant to *28 U.S.C. § 1407*(a). Plaintiff Barr Laboratories, Inc. ("plaintiff") originally filed its suit on March 9, 1998 in the Southern District of New York against defendant DuPont Merck Pharmaceutical Company ("defendant"). n1 (D.I. 1 (98 Civ. 1695)) Plaintiff is a generic pharmaceutical manufacturer incorporated in New York with a principal place of business in Pomona, New York. (D.I. 1, P 5 (98 Civ. 1695)) Defendant is a partnership between E.I. DuPont de Nemours & Co. (a Delaware corporation with a principal place of business in Wilmington, Delaware) and [*4] Merck & Co. (a New Jersey corporation with its principal place of business in Whitehouse Station, New Jersey). (D.I. 1, P 6 (98 Civ. 1695)) Defendant manufactures and distributes pharmaceuticals and has its principal place of business in Wilmington, Delaware. (D.I. 1, P 6 (98 Civ. 1695))

n1 By letter dated July 30, 1998, the court was informed that defendant had changed its name to DuPont Pharmaceuticals Company.

Class plaintiffs Kusnerik and Altman filed class action complaints in the District of Delaware, (D.I. 1 (C.A. 97-659) (C.A. 97-670)) while class plaintiffs Tischler and Steckel n2 each filed class action suits against defendant in the Southern District of Florida (D.I. 1 (98-178-Civ.)) and the Western District of Pennsylvania (D.I. 1 (98-697)), respectively (collectively, "class plaintiffs"). Class plaintiffs purport to represent a class of more than 1.8 million persons who purchased Coumadin for personal use at any time during the period beginning on or about July 28, 1997 to the present. (D.I. 1, P [*5] 6 (C.A. 97-659))

n2 Class plaintiff Steckel sued defendants DuPont Pharmaceutical Company, E.I. DuPont de Nemours & Company, and Merck & Company, Inc. For purposes of this memorandum opinion, these defendants shall be referred to in the singular.

In this action, plaintiff and class plaintiffs allege that defendant engaged in unlawful monopolization and attempted monopolization in violation of § 2 of the Sherman Act. *15 U.S.C. § 2*. Plaintiff also asserts claims against defendant founded on § 43(a) of the Lanham Act, *15 U.S.C. § 1125*(a), § 2(c) of the Robinson-Patman Act, *15 U.S.C. § 13*(c), the New York General Business Law, *N.Y. Gen. Bus. L. §§ 349* and 350, and common law product disparagement and tortious interference with prospective business advantage. Plaintiff and class plaintiffs seek trebled damages under § 4 of the Clayton Act. Class plaintiffs also seek injunctive relief under § 16 of the Clayton Act. Additionally, class plaintiffs Tischler and Steckel allege that defendant's actions violated [*6] various state laws.

Currently before the court is defendant's motion to dismiss plaintiff's claims and class plaintiffs' claims for failure to state a claim upon which relief can be granted. *Fed.R.Civ.P. 12(b)(6)*. The court has federal question jurisdiction pursuant to *28 U.S.C. §§ 1331* and 1337. The court also has supplemental jurisdiction over the state law claims pursuant to *28 U.S.C. § 1367*. For the reasons that follow, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted.

II. BACKGROUND

The following facts are taken from plaintiff's and class plaintiffs' complaints and, for purposes of this motion to dismiss, are accepted as true. This suit arises from plaintiff's attempt to market a generic version of defendant's successful and profitable blood thinner known as "Coumadin." Coumadin is the brand name for defendant's formulation of warfarin sodium -- an anticoagulant agent, taken orally, prescribed for patients suffering from thrombosis, embolisms, and other blood-clotting disorders. (D.I. 1, PP 1, 9 (98 Civ. 1695)) Warfarin sodium (either in generic form or as the [*7] active ingredient in Coumadin) is classified as a Narrow Therapeutic Index ("NTI") drug because too little of it can lead to stroke or cardiac arrest and too much of it can cause internal bleeding. (D.I. 1, P 19 (98 Civ. 1695)) Consequently, treating physicians must carefully monitor patients taking either Coumadin or generic warfarin sodium.

Although the patent protection for Coumadin expired on April 2, 1962, Coumadin has dominated the oral anticoagulant market for over thirty years. (D.I. 1, PP 11, 12 (98 Civ. 1695)) In fact, until plaintiff's generic warfarin sodium tablets were introduced in 1997, no equivalent product competed with Coumadin for several years. (D.I. 1, PP 11, 69 (98 Civ. 1695)) Defendant's annual Coumadin sales are approximately $ 500 million. (D.I. 1, P 24 (C.A. 97-659)) According to class plaintiffs, the cost of Coumadin has escalated 300% to 400% in the past ten years. (D.I. 1, P 25 (C.A. 97-659))

Plaintiff and class plaintiffs allege that defendant, anticipating a loss of market share to plaintiff's cheaper warfarin sodium tablets, n3 "implemented a multifaceted attack against generic substitutes generally and [plaintiff's] product specifically, the cumulative [*8] effect of which has been to raise [plaintiff's] costs to enter the anticoagulant market and to hinder [plaintiff's] ability to penetrate the market effectively." (D.I. 1, P 16 (98 Civ. 1695); D.I. 1, P 33 (C.A. 97-659)) Plaintiff and class plaintiffs contend that defendant engaged in allegedly anticompetitive tactics in order to preserve its monopoly in the oral anticoagulant market. Class plaintiffs claim that, due to defendant's anticompetitive activities, they have paid inflated prices for Coumadin. (D.I. 1, P 51 (C.A. 98-178))

n3 Plaintiff notes in its complaint that

> the introduction of a generic alternative to a brand name product typically results in significant reduction in the brand name product's market share within the first year. The high level of a generic drug's market penetration is due to its lower cost, generic substitution laws, and preferred status in third-party reimbursement plans.
>
> (D.I. 1, P 15 (98 Civ. 1695))

More specifically, in May 1995 plaintiff filed an Abbreviated New [*9] Drug Application ("ANDA") with the FDA seeking approval to manufacture and distribute generic warfarin sodium tablets. (D.I. 1, P 21 (98 Civ. 1695)) In October of 1996, defendant filed a Petition for Stay with the FDA asking it to postpone approval for all generic warfarin sodium products pending the adoption of stricter bioequivalence standards. n4 (D.I. 1, P 22 (98 Civ. 1695)) In its Petition for Stay, defendant argued that the FDA's current bioequivalence standards were inadequate to assure the bioequivalence of Coumadin with other generic warfarin sodium drugs. Defendant asked the FDA to adopt a stricter "individual" bioequivalence standard, rather than an "average" standard, to determine whether generic warfarin sodium products were bioequivalent to Coumadin. n5

> n4 Bioequivalence "means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 29 C.F.R. § 320.1 (e) (1998).

[*10]

n5 Plaintiff and class plaintiffs characterize this Petition for Stay as "baseless" and designed specifically to inflict competitive injury on plaintiff by forcing it to conduct time-consuming and costly studies before it could enter the oral anticoagulant market. (D.I. 1, P 68 (98 Civ. 1695); D.I. 1, P 33 (C.A. 97-659))

The FDA denied defendant's petition, stating that it was

> in the process of considering individual bioequivalence testing for all generic drugs. At this time, however, it is neither reasonable nor in the interest of the public to impose such testing standards on generic applicants because the approach has not been fully developed and current methods are effective in establishing bioequivalence between drug products.

(D.I. 1, P 29 (98 Civ. 1695) (citing letter from FDA to defendant of 3/25/97, at 3)) The FDA has since issued a request for public comment on a preliminary draft proposal that "recommends that the individual bioequivalence approach be used by sponsors of ANDAs . . . to assess bioequivalence between a generic and a listed drug." *62 Fed. Reg. 67880, 67881* [*11] (Dec. 17, 1997). n6

n6 In ruling on a motion to dismiss, a court may consider only the allegations contained in the complaint, exhibits attached thereto, and matters of public record. See 5A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1357 (2d ed. 1990). Where, as here, the parties have provided the court with undisputedly authentic regulatory documents, the court may consider them in reviewing a motion to dismiss. See *City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998);* see also *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).*

During the same period of time, defendant filed a petition with the United States Pharmacopeial Convention, Inc. ("USP"), urging the USP to adopt Coumadin's narrow content uniformity specifications (which are stricter than those the USP currently requires) as the industry standard for all warfarin sodium drugs. n7 (D.I. 1, P 24 (98 Civ. 1695)) The USP publishes the official [*12] compendium of pharmaceuticals in the United States, and listing in the USP is essential to the acceptance of a pharmaceutical product by the medical community. (D.I. 1, P 24 (98 Civ. 1695)) The USP rejected the petition.

n7 Plaintiff further alleges that defendant's petitioning of the USP to narrow the content uniformity specifications for warfarin sodium tablets was "an obvious attempt to impose stricter regulations on a new competitor" designed to thwart plaintiff's entry into the oral anticoagulant market. (D.I. 1, PP 23, 24 (98 Civ. 1695))

Plaintiff began marketing its warfarin sodium tablets on July 25, 1997. (D.I. 1, P 26 (98 Civ. 1695)) Despite its unsuccessful petitioning efforts with the FDA and the USP, defendant allegedly issued communications setting forth its position that Coumadin is safer and more efficacious than plaintiff's warfarin sodium tablets. It is asserted by plaintiff that:

. Defendant revised its "Couma Care" computer software (a promotional system designed to assist health care [*13] practitioners in monitoring patients using Coumadin) to include warnings about switching to generic substitutes. (D.I. 1, P 18 (98 Civ. 1695); D.I. 1, P 35 (C.A. 97-659))

. Defendant created and funded the Health Alliance for NTI Patient Safety to lobby state legislatures, formularies, and pharmacy boards to exclude NTI drugs from state generic substitution laws. (D.I. 1, P 19 (98 Civ. 1695))

. Defendant initiated a publicity campaign touting Coumadin's "tighter than USP" content uniformity

standards. (D.I. 1, P 24 (98 Civ. 1695))

. Defendant issued a press release which contained the following assertions:

> if warfarin products are interchanged, patients should receive additional blood tests to ensure the amount of drug in their bloodstream is appropriate for their condition. It should be noted that this warning is included in the FDA-approved package insert for both [defendant's] Coumadin and for [plaintiff's] generic product.
>
> * * *
>
> while [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and the future health of over two million patients who depend on Coumadin everyday.

[*14]

(D.I. 1, PP 27, 31 (98 Civ. 1695) (citing defendant's press release of 7/28/97, at 2))

. Defendant offered for review to health care professionals a slide presentation in which defendant claimed that, regardless of FDA findings of bioequivalence, generic drugs may not be therapeutically equivalent to their branded counterparts. (D.I. 1, P 29 (98 Civ. 1695))

. Defendant used the FDA's Adverse Drug Event ("ADE") reporting system in order to generate fear over switching from Coumadin to generic warfarin sodium. (D.I. 1, P 35 (98 Civ. 1695)) Specifically, defendant issued a press release in which it stated that "it has submitted to the FDA more than 70 spontaneous reports from health care providers of adverse drug events temporally associated with patients who had been switched from one drug to the other." n8 (D.I. 1, P 36 (98 Civ. 1695) (citing the press release of 12/3/97, at 1))

> n8 Plaintiff contends that these ADE reports were rife with lies and mischaracterizations and were "designed to defame plaintiff both at the FDA and in the marketplace." (D.I. 13 at 13 (98 Civ. 1695)) Plaintiff alleges that some of these ADE reports did not even involve its generic warfarin sodium tablets. (D.I. 1, P 38 (98 Civ. 1695)) Plaintiff further claims that defendant solicited a large number of reports or reported events that the health care providers in question did not consider "adverse events;" indeed, many health care providers were unaware of being credited with ADE reports. (D.I. 1, PP 39, 41, 42 (98 Civ. 1695))

[*15]

The FDA admonished defendant for its assertions that additional blood testing was required following a switch from Coumadin to generic warfarin sodium. (D.I. 1, P 28 (98 Civ. 1695)) For instance, in objecting to defendant's slide presentation, the FDA stated:

> It is misleading to suggest that generic products that FDA has determined are bioequivalent to Coumadin, may not be therapeutically equivalent to the reference product without substantial evidence to support such a claim. All FDA approved dosage forms of generic drugs classified as therapeutically equivalent . . . can be substituted for the reference product with the full expectation that the substituted product will produce the same clinical effect and safety profile.

(D.I. 1, P 29 (98 Civ. 1695) (citing FDA letter of 8/26/97, at 2))

In addition to its anticompetitive communications, defendant allegedly entered into a variety of anticompetitive rebate, "market retention" agreements, and "inventory management" agreements with pharmacy benefit managers, retail pharmacies, and pharmaceutical wholesalers in order to preserve its monopoly in the oral anticoagulant market. (D.I. 1, PP 53-62 (98 Civ. 1695)) According [*16] to plaintiff, defendant offered and paid rebates to pharmacy benefit managers n9 to ensure the dispensing of Coumadin rather than plaintiff's generic warfarin sodium. (D.I. 1, P 54 (98 Civ. 1695)) It is alleged in this regard that defendant rewarded large

pharmacy and drug store chains for stocking Coumadin as a substantial part of their oral anticoagulant inventory. (D.I. 1, P 56 (98 Civ. 1695)) The "inventory management" agreements offered wholesalers "unprecedented rebates" and "extended payment terms" for purchases of specific quantities of Coumadin during July, August, and September of 1997. (D.I. 1, P 59 (98 Civ. 1695)) Defendant allegedly timed these agreements to coincide with plaintiff's introduction of its generic warfarin sodium. (D.I. 1, P 60 (98 Civ. 1695)) Defendant has offered similar "inventory management" incentives covering purchases in 1998. (D.I. 1, PP 60, 62 (98 Civ. 1695)) Plaintiff argues that these agreements have had the net effect of excluding its generic warfarin sodium from the oral anticoagulant market. (D.I. 1, P 57 (98 Civ. 1695))

n9 Pharmacy benefit managers dictate which brands of pharmaceuticals will be dispensed to patients of managed care organizations and insurance companies. According to plaintiff, "almost three-quarters of all the prescriptions dispensed in this country are affected by such third-party adjudication." (D.I. 1, P 54 (98 Civ. 1695))

[*17]

III. POST-TRANSFER APPLICABLE LAW

In the leading case on choice of law in multidistrict transfers, the District of Columbia Circuit Court has noted that "the law of a transferor forum on a federal question . . . merits close consideration, but does not have start decisis effect in a transferee forum situated in another circuit." *In re Korean Airlines Disaster, 265 U.S. App. D.C. 39, 829 F.2d 1171, 1176 (D.C. Cir. 1987)*, aff'd on other grounds sub nom. *Chan v. Korean Airlines Ltd., 490 U.S. 122, 104 L. Ed. 2d 113, 109 S. Ct. 1676 (1989)*. In *In re Donald J. Trump Casino Sec. Litig., 7 F.3d 357 (3d Cir. 1993)*, the Third Circuit assumed, without deciding, that the district court's adoption of the District of Columbia Circuit's rationale was proper. See *id. at 367 n.8*. The Second Circuit also has held that a transferee federal court should apply its interpretations of federal law, not the transferor forum's constructions of federal law. See *Coker v. Pan Am. World Airways, Inc., 950 F.2d 839, 847 (2d Cir. 1991)* (concerning transfer motion pursuant to *28 U.S.C. § 157*(b)(5)).

Accordingly, the court will apply Third Circuit precedent to the federal questions [*18] presented by these consolidated cases. Where no Third Circuit precedent exists, the court will give careful consideration to the law of the transferor forum. As for the state law issues presented in this case, the rule of *Van Dusen v. Barrack, 376 U.S. 612, 11 L. Ed. 2d 945, 84 S. Ct. 805 (1964)*, requires the court to apply the substantive state law of the jurisdiction in which the action was filed.

IV. STANDARD OF REVIEW

In analyzing a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all material allegations of the complaint, and it must construe the complaint in favor of the plaintiff. See *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998)*. "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. Claims may be dismissed pursuant to a Rule 12(b)(6) motion only if the plaintiff cannot demonstrate any set of facts that would entitle it to relief. See *Conley v. Gibson, 355* [*19] *U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957)*. The moving party has the burden of persuasion. See *Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)*. With these rules in mind, the court turns to an examination of the sufficiency of plaintiff's and class plaintiffs' complaints.

V. SUFFICIENCY OF PLAINTIFF'S COMPLAINT

Defendant argues that the court should dismiss plaintiff's monopolization and attempted monopolization claims. Further, defendant argues that its conduct does not state a claim under either the Lanham Act or under § 2(c) of the Robinson-Patman Act. Defendant also asserts that plaintiff has failed to allege the necessary elements of the state law business tort claims asserted against defendant. The court will address each of these issues in turn.

A. Plaintiff's Monopolization and Attempted Monopolization Claims

Section 2 of the Sherman Act punishes "every person

who shall monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." *15 U.S.C. § 2* ("Sherman § 2"). The offense of monopolization under § 2 of the Sherman Act requires proof [*20] of: "(1) possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power, as distinguished from the growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp., 384 U.S. 563, 570-71, 16 L. Ed. 2d 778, 86 S. Ct. 1698 (1966).* In order to prevail on an attempted monopolization claim, a plaintiff must show "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456, 122 L. Ed. 2d 247, 113 S. Ct. 884 (1993).*

Defendant does not dispute that it enjoys monopoly power in the market for oral anticoagulants. At issue is whether defendant's actions amount to predatory conduct or the willful acquisition of monopoly power. Defendant argues that its petitions to federal and state legislatures and administrative bodies, as well as its statements to health care providers and the general public, do not constitute predatory conduct because they enjoy immunity from antitrust liability under the Noerr-Pennington [*21] doctrine. Defendant also claims that such activity is not "exclusionary" under Sherman § 2.

1. The Noerr-Pennington Doctrine

In *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 5 L. Ed. 2d 464, 81 S. Ct. 523 (1961),* the Supreme Court held that concerted efforts to restrain or monopolize trade by petitioning the government enjoy antitrust immunity. See also *United Mine Workers v. Pennington, 381 U.S. 657, 670, 14 L. Ed. 2d 626, 85 S. Ct. 1585 (1965)* (holding that "joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). The Court has broadened Noerr-Pennington immunity to include the petitioning of the executive and judicial branches of government. n10 See *California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513, 30 L. Ed. 2d 642, 92 S. Ct. 609 (1972).* The Supreme Court generally has refused to impose antitrust liability for petitioning the government because doing so would infringe upon the First Amendment's protection of free speech, chill public involvement in our representative government, and impermissibly extend the Sherman Act to cover [*22] political as well as commercial activity. See *Noerr, 365 U.S. at 137-38;* see also 10 Earl W. Kintner & Joseph P. Bauer, Federal Antitrust Law § 77.1, at 187-88 (1994).

> n10 The Supreme Court has extended Noerr-Pennington immunity as well to the petitioning of nongovernmental bodies when they perform quasi-public duties. See *Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 100 L. Ed. 2d 497, 108 S. Ct. 1931 (1988).* The USP is a private entity, but it publishes the official compendium of pharmaceuticals in the United States. (D.I. 1, P 24 (98 Civ. 1695)) Since the USP promulgates standards governing pharmaceuticals (through procedures similar to those used by administrative agencies), the court will analyze the defendant's petition to the USP as it would a petition before an administrative agency.

The Supreme Court has ruled, however, that frivolous and illegitimate petitioning of government bodies does not enjoy Noerr-Pennington immunity. In *City of Columbia v. Omni Outdoor* [*23] *Advertising, Inc., 499 U.S. 365, 113 L. Ed. 2d 382, 111 S. Ct. 1344 (1991),* the Court held that the "sham exception" to Noerr-Pennington immunity applies when "persons use the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon." *Id. at 380.* The Court has enunciated a two-part test to identify sham proceedings. See *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 123 L. Ed. 2d 611, 113 S. Ct. 1920 (1993)* ("PRE").

The first prong of the test requires a court to determine n11 if the suit or proceeding is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id. at 60.* A suit is not objectively baseless if "an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome." Id. An antitrust plaintiff cannot prove a sham "merely by showing that its competitor's 'purposes were to delay [the plaintiff's] entry

into the market.'" *Id. at 59-60* (quoting *Omni Outdoor, 499 U.S. at 381 (1991)).*

> n11 Plaintiff argues the "baselessness" inquiry is inherently a question of fact and, therefore, inappropriate for resolution by the court. (D.I. 13 at 15 (98 Civ. 1695)) The Supreme Court, however, has found that a court may decide, as a matter of law, whether a party invoking Noerr-Pennington immunity had probable cause to bring an allegedly baseless suit. See *PRE, 508 U.S. at 63.* A finding of probable cause "compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit." Id.

[*24]

Only if challenged litigation is "baseless" may courts examine the subjective motivations of the litigant. The second prong of the test invites courts to determine whether a defendant has anticompetitive motivations. Specifically, this second prong instructs courts to "focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" *PRE, 508 U.S. at 60-61* (quoting *Noerr, 365 U.S. at 144)).*

a. Defendant's Petition for Stay to the FDA

Plaintiff alleges that defendant's petition to the FDA was baseless in that it lacked expert testimony and evidentiary support. In support of its position, plaintiff quotes the former head of the FDA's Office of Generic Drugs as stating that defendant's Petition for Stay was "in the class of an economic challenge" rather than a scientific one. (D.I. 1, P 23 (98 Civ. 1695)) Plaintiff complains that defendant's "maneuverings before the FDA delayed the introduction of [its] product by several months and imposed substantial additional costs on [it] and loss of sales revenue." (D.I. 1, P 23 (98 Civ. 1695))

Other than conclusory allegations that defendant's petition lacked [*25] evidentiary support, plaintiff offers no basis for its assertion that defendant initiated its Petition for Stay without any "realistic expectation of success on the merits." *PRE, 508 U.S. at 60.* The complaint reveals that defendant's Petition for Stay proposed more stringent bioequivalency standards governing generic substitutes for Coumadin, but does not allege that defendant included fraudulent or misleading information in its Petition for Stay.

Without more, plaintiff cannot show that defendant's Petition for Stay lacked "a realistic expectation of success on the merits." See *PRE, 508 U.S. at 60.* Indeed, the complaint suggests that an objective litigant could conclude that defendant's Petition for Stay was "reasonably calculated to elicit a favorable outcome." Id. The complaint reveals that defendant petitioned the FDA for adoption of narrower bioequivalency standards -- standards that the FDA had the exclusive power to set. In its ten page reply to the Petition for Stay, the FDA did not find the petition frivolous or unreasonable. Indeed, the FDA granted defendant's request that ANDA applicants be required to conduct certain tests unrelated to bioequivalency. Moreover, [*26] the FDA later proposed to adopt the very bioequivalency standards recommended by defendant in its Petition for Stay. See *62 Fed. Reg. 67880, 67881* (Dec. 17, 1997).

The Supreme Court has recognized that "a successful 'effort to influence government action . . . certainly cannot be characterized as a sham.'" *PRE, 508 U.S. at 58* (quoting *Allied Tube, 486 U.S. at 502).* Plaintiff has failed to provide a basis for inferring that defendant's Petition for Stay was anything other than a successful attempt to secure more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant's motion to dismiss plaintiff's antitrust claim, as the claim relates to the Petition for Stay, is granted.

b. Defendant's Petition to the USP

Likewise, plaintiff's complaint is devoid of any facts from which the court could infer that defendant's USP petition lacked a "realistic expectation of success on the merits." *PRE, 508 U.S. at 60.* Plaintiff's complaint reveals only that defendant's petition requested a specific form of relief uniquely within the competence of the USP. Plaintiff presents no evidence that would support an inference of frivolousness or baselessness. [*27] Although the USP denied defendant's petition, the "court must resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE, 508 U.S. at 61 n.5* (internal

quotations and citations omitted). Defendant's motion to dismiss plaintiff's antitrust claim, insofar as it is based on defendant's petition to the USP, is granted.

2. Defendant's Alleged Abuse of the FDA's ADE Reporting System

Plaintiff alleges that defendant submitted fraudulent ADE reports to the FDA and used these ADE reports in administrative hearings before state agencies. (D.I. 1, PP 38, 46 (98 Civ. 1695)) Defendant argues that these ADE reports, even if fraudulent, also enjoy Noerr-Pennington immunity. The Supreme Court, however, has declined to extend Noerr-Pennington immunity to deceptive practices before adjudicatory bodies like administrative agencies or courts. In California Motor Transport, the Court noted that "misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." *California Motor Transp., 404 U.S. at 513;* see also [*28] *Allied Tube, 486 U.S. at 500* (remarking that "in less political arenas, unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations"). Administrative agencies, like state pharmacy boards, act in an adjudicatory capacity when they consider petitions urging the adoption of stricter standards governing NTI drugs.

Accepting the facts contained in the complaint as true, the court can infer that defendant used fraudulent and misleading ADE reports before state administrative agencies. Supplying fraudulent information to state agencies "threatens the fair and impartial functioning of [such] agencies and does not deserve immunity from the antitrust laws." *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1261 (9th Cir. 1982).* Insofar as plaintiff's Sherman § 2 claim rests on defendant's use of fraudulent ADE reports before state agencies, defendant's motion to dismiss is denied.

Plaintiff's complaint also alleges that defendant used the ADE reports to urge state legislators to exclude generic warfarin sodium from state generic substitution laws. False statements made to legislators [*29] and legislative bodies in an effort to change government policy are protected by Noerr-Pennington immunity. In Noerr, the Court noted that deception in the political arena, "reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Noerr, 365 U.S. at 145.* False statements in the political arena enjoy antitrust immunity because "there is an emphasis on debate in the political sphere, which can accommodate false statements and reveal their falsity." *Clipper Exxpress, 690 F.2d at 1261.* Consequently, plaintiff may not rest its monopolization claims on defendant's misrepresentations to state legislators or legislative bodies. n12

> n12 Plaintiff argues that the "commercial exception" to Noerr-Pennington immunity subjects defendant to antitrust liability for its misrepresentations to state legislatures that purchased pharmaceuticals for its citizens. Because neither the Second nor the Third Circuits have recognized the existence of this exception to Noerr-Pennington immunity and because the court has denied defendant's motion to dismiss on other grounds, the court declines to address the validity of plaintiff's "commercial exception" theory.

[*30]

3. Defendant's Statements to the General Public and the Health Care Industry

Defendant argues that its statements to the general public and to the health care industry, even if false and misleading, are protected by the Noerr-Pennington doctrine because they were made as part of a campaign "to shape public policy regarding patient safety in the use of NTI drugs." (D.I. 12 at 10 (98 Civ. 1695)) Alternatively, defendant argues that its "statements of opinion" do not give rise to antitrust liability because they are not exclusionary conduct.

a. Noerr-Pennington Immunity

The Supreme Court has held that, where an anticompetitive restraint arises solely from private action, "the restraint cannot form the basis for antitrust liability if it is 'incidental' to a valid effort to influence government action." *Allied Tube, 486 U.S. at 499* (citing *Noerr, 365 U.S. at 143)* (emphasis added)); see also *Massachusetts School of Law, Andover v. American Bar Ass'n, 107 F.3d 1026, 1035 (3d Cir. 1997)* ("MSL"). The Supreme Court has recognized, however, that "the validity of such efforts, and thus the applicability of Noerr immunity, varies with the context and [*31] nature of the activity." *Allied Tube, 486 U.S. at 499.*

The question at bar is whether defendant's public statements were incidental to valid efforts to persuade government agencies to adopt more stringent bioequivalency standards for generic warfarin sodium drugs. Defendant argues that its public statements were "part and parcel" of its campaign to influence public officials and its statements, even if false and misleading, enjoy Noerr-Pennington immunity. (See D.I. 12 at 10 (98 Civ. 1695))

Defendant's attempts to influence public officials centered on the establishment of stricter bioequivalency standards. In contrast, defendant's public statements warned consumers of "medical-legal" exposure in switching from Coumadin to generic warfarin sodium and urged doctors to conduct additional blood tests following a switch to generic warfarin sodium. (See D.I. 1, PP 18, 34 (98 Civ. 1695)) Defendant impugned the quality of plaintiff's generic warfarin sodium and issued press releases publicizing allegedly false ADE reports related to generic warfarin sodium. (See D.I. 1, PP 31, 46 (98 Civ. 1695))

In Noerr, where the railroads published false and misleading public [*32] statements about the trucking industry, those statements were directly related to the railroads' efforts to obtain legislation regarding truck weight limits and increased taxes on heavy trucks. The railroads' publicity campaign addressed the damage done to highways by overweight trucks, the failure of the trucking industry to pay its fair share of road maintenance costs, and the hazards created by overweight trucks. See *Noerr, 365 U.S. at 131.* Indeed, the Supreme Court held that **"at least insofar as the railroads's [publicity] campaign was directed toward obtaining governmental action,** its legality was not at all affected by any anticompetitive purpose it may have had." *Id. at 139-40* (emphasis added). In the case at bar, the court cannot infer at this stage of the proceedings that the totality of defendant's public statements were "part and parcel" of its efforts to secure more stringent bioequivalency standards for warfarin sodium drugs. For purposes of this motion to dismiss, therefore, the court finds that defendant's statements to the general public and to the health care community do not warrant Noerr-Pennington immunity.

b. Sherman § 2

Defendant cites [*33] MSL for the proposition that the Third Circuit has refused to construe false and misleading speech as exclusionary activity under Sherman § 2. In MSL, the Massachusetts School of Law argued that it was injured by the stigmatic effect of the ABA's refusal to accredit it. See *MSL, 107 F.3d at 1037-38.* It claimed this stigmatic effect arose from the ABA's attempts to convince states to make graduation from an ABA accredited law school necessary for bar admission. The law school characterized the ABA's efforts as a "campaign to convey the idea that ABA accreditation is the sine qua non of quality." *Id. at 1037.* In affirming the district court's granting of summary judgment in favor of the ABA, the court found that the complained-of speech amounted to nothing more than "the ABA's justification of its accreditation decisions." Id.

Unlike the facts in MSL, where the ABA was found merely to have defended its own standard setting and accreditation decisions, defendant's speech at issue is directed at consumers and directly attacks the quality and substitutability of plaintiff's generic warfarin sodium. The court finds the Third Circuit's decision in MSL inapposite [*34] under these circumstances.

Other courts have recognized that misleading advertising can rise to the level of anticompetitive conduct if the plaintiff "overcome[s] a presumption that the effect on competition of such a practice was de minimis." *Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 288 n.41 (2d Cir. 1979)*(quoted in *National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs., 850 F.2d 904, 916 (2d Cir. 1988)).* The Second Circuit, in a case factually similar to the one at bar, held that a plaintiff may overcome the de minimis bar (and a motion to dismiss) by "cumulative proof that [defendant's] representations were (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible of neutralization or other offset by rivals." *Ayerst Labs., 850 F.2d at 916.* In the absence of Third Circuit precedent, the court finds these factors helpful in determining whether defendant's allegedly false and misleading statements rise to the level of unlawful exclusionary conduct.

In the present case, plaintiff's complaint [*35] satisfies each of the above six factors. The complaint alleges that defendant's extensive publicity campaign contained false misrepresentations. Plaintiff claims that

these material misrepresentations were made to the general public in order to induce potential consumers to avoid purchasing generic warfarin sodium. On a motion to dismiss, plaintiff is entitled to the inference that the general public lacked the sophistication to discern that defendant's statements about bioequivalency were false. Although defendant argues that its statements were "readily susceptible to neutralization" by plaintiff and the FDA (D.I. 14 at 19-20) (98 Civ. 1695)), defendant is not entitled to this inference on a motion to dismiss. Moreover, plaintiff's dismal market share belies this assertion. (See D.I. 1, P 16 (98 Civ. 1695)).

Consequently, the court finds that defendant's allegedly false and misleading speech had more than a de minimis effect on competition. Plaintiff may premise its Sherman § 2 claim on defendant's public statements.

4. Defendant's Rebate and Market Retention Agreements

Plaintiff claims that defendant's various rebate and market retention agreements also violate [*36] § 2 of the Sherman Act. Plaintiff argues that these agreements, in combination with defendant's misleading statements, have had the "synergistic effect" of harming competition in the oral anticoagulant market. (D.I. 13 at 27-29 (98 Civ. 1695)) Defendant contends that its price discounts and its allegedly deceptive statements "cannot possibly be viewed as working together 'synergistically' to produce an anticompetitive result because the theories of competitive harm are fundamentally at odds with each other." (D.I. 14 at 21 (98 Civ. 1695))

In analyzing an antitrust complaint, the court recognizes that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699, 8 L. Ed. 2d 777, 82 S. Ct. 1404 (1962).* The court finds that the combined effect of defendant's conduct could harm competition in the oral anticoagulant market. Those consumers that defendant failed to scare away from generic warfarin sodium could be "bought off" by defendant's rebate and inventory management incentives. Thus, defendant's [*37] allegedly misleading statements, coupled with financial disincentives to purchase generic warfarin sodium, could form part of an unlawful, multifaceted effort to hinder competition in the oral anticoagulant market.

In sum, plaintiff may premise its Sherman § 2 claim on defendant's use of allegedly fraudulent ADE reports before state agencies, defendant's allegedly false and misleading statements to the general public and the health care community, and defendant's use of rebates and market retention agreements as part of its allegedly multifaceted effort to restrain trade in the oral anticoagulant market. Plaintiff may not base its Sherman § 2 claim on defendant's petitions to the FDA or USP or defendant's use of allegedly fraudulent ADE reports before state legislatures.

B. Plaintiff's Lanham Act Claim

Plaintiff claims that defendant violated § 43(a) of the Lanham Act by misrepresenting the nature, characteristics, and quality of plaintiff's product to "the public at large, wholesalers, pharmacies and health care professionals, as well as state and federal regulators." (D.I. 1, P 73 (98 Civ. 1695)) The Lanham Act imposes civil liability on those who, "**in commercial advertising** [*38] **or promotion**, misrepresent[] the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services or commercial activities. . . ." *15 U.S.C. § 1125*(a)(1)(B) (emphasis added). The Act protects "consumers and competitors from a myriad of misrepresentations of products and services in commerce." *Wojnarowicz v. American Family Ass'n, 745 F. Supp. 130, 141 (S.D.N.Y. 1990)* (quoting *Allen v. National Video, Inc., 610 F. Supp. 612, 625 (S.D.N.Y. 1985)).*

Defendant contends that its public statements are immune from Lanham Act liability because they were not made in the context of "commercial advertising or promotion." Alternatively, defendant argues that, even if its statements occurred in the context of commercial advertising or promotion, its commercial speech was "inextricably intertwined" with protected First Amendment speech designed to influence public policies regarding warfarin sodium drugs. The court must determine whether defendant's public statements occurred "in commercial advertising or promotion" and, if so, whether those statements enjoy First Amendment protection from Lanham Act liability.

1. "In Commercial Advertising [*39] or Promotion"

There is a dearth of case law addressing whether a defendant's communications occurred "in commercial

advertising or promotion." This is so because "generally, a plaintiff can easily satisfy its burden of proving that the complained-of representation was made in 'commercial advertising or promotion' by pointing to paid advertisements by a commercial defendant on television or radio, or in newspapers or magazines." *Gordon & Breach Science Publishers S.A. v. American Inst. of Physics, 859 F. Supp. 1521, 1532 (S.D.N.Y. 1994).* Here, defendant's allegedly false and misleading statements did not appear in the classic form of an advertising campaign. Instead, they were made in the context of press releases, computer software, letters, and facsimile transmissions.

Courts that have addressed the "commercial advertising or promotion" issue have concluded that "the [Lanham] Act's reach is broader than the 'classic advertising campaign.'" *Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1384 (5th Cir. 1996)* (quoting *Gordon & Breach, 859 F. Supp. at 1534 (S.D.N.Y. 1994)).* Courts, for instance, have found § 43(a) applicable to the fundraising letters of a nonprofit [*40] pregnancy counseling group, see *Birthright v. Birthright, Inc., 827 F. Supp. 1114, 1137-38 (D.N.J. 1993),* and to an individual's "bad-mouthing" of her former company in telephone calls to friends and former colleagues, see *National Artists Management Co. v. Weaving, 769 F. Supp. 1224, 1234-35 (S.D.N.Y. 1991).*

The district court in Gordon & Breach, after an extensive analysis of case law and legislative history, distilled four factors necessary to satisfy the "commercial advertising or promotion" requirement of § 43(a)(1)(B). The statements must be

> (1) commercial speech; (2) by a defendant who is in commercial competition with plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services . . . (4) . . . disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within that industry.

Gordon & Breach, 859 F. Supp. at 1535-36; accord *Seven-Up Co., 86 F.3d at 1384* (finding the district court's analysis "accurate and sound").

Applying this analysis to the facts at bar, defendant's statements satisfy at least three Gordon & Breach factors. Defendant competes with plaintiff [*41] in the oral anticoagulant market. Plaintiff sufficiently alleges that defendant's statements influenced doctors, pharmacists, and others to purchase or prescribe Coumadin instead of generic warfarin sodium. Defendant disseminated its statements to such a wide audience of the healthcare industry that plaintiff is entitled to the inference that defendant engaged in advertising or promotion. (See, e.g., D.I. 1 at P (alleging that defendant faxed a misleading letter to 45,000 pharmacists))

Turning to the final factor, the "commercial speech" requirement, the Supreme Court has defined "commercial speech" as "speech proposing a commercial transaction." *United States v. Edge Broad. Co., 509 U.S. 418, 426, 125 L. Ed. 2d 345, 113 S. Ct. 2696 (1993);* see also *Board of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 473-74, 106 L. Ed. 2d 388, 109 S. Ct. 3028 (1989)* (characterizing the proposal of a commercial transaction as "the test for identifying commercial speech") (emphasis added). n13 Defendant contends that none of its statements proposed any commercial transactions; rather, its statements conveyed merely "that care should be taken in switching between warfarin [*42] products given warfarin sodium's status as an NTI drug." (D.I. 14 at 24) A review of plaintiff's complaint indicates that not all of defendant's statements are subject to such an innocuous interpretation.

> n13 Defendant's petitions to the FDA, the USP, and those state agencies that merely set standards governing the bioequivalency of generic drugs do not fall within this definition. Plaintiff has not alleged, nor could it, that any statements made to these regulatory bodies proposed a commercial transaction.

For instance, defendant's "Couma Care" computer software included praise for the "high quality" of Coumadin while warning of the "risks" and "medical-legal exposure" entailed in switching from Coumadin to generic warfarin sodium. (D.I. 1, P 18 (98 Civ. 1695)) In a press release coinciding with the introduction of plaintiff's warfarin sodium tablets, defendant claimed that "while [plaintiff] focuses on producing a cheaper product to help save money, [defendant] focuses on patient safety and education and [*43] the future health of over two million patients who

depend on Coumadin everyday." (D.I. 1, P 31 (98 Civ. 1695)) Defendant also allegedly employed false ADE reports to dissuade pharmacists and state pharmacy boards from purchasing plaintiff's generic warfarin sodium.

Statements such as these satisfy the court that defendant's press releases and other communications were not confined solely to defendant's efforts to influence public policy on generic substitution of warfarin sodium drugs. Plaintiff at this stage of the proceedings is entitled to the inference that defendant's statements "proposed a commercial transaction" by (1) denigrating plaintiff's generic warfarin sodium, (2) stressing the dangers of substituting generic warfarin sodium for Coumadin, and (3) touting Coumadin's "high quality" and "tighter than USP" content uniformity specifications. (See D.I. 1, PP (98 Civ. 1695))

In order to state a prima facie case under § 43(a) of the Lanham Act, the Third Circuit has ruled that a plaintiff must show

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to [*44] deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods travelled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of goodwill, etc.

U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922-23 (3d Cir. 1990) (quoting *Max Daetwyler Corp. v. Input Graphics, Inc., 545 F. Supp. 165, 171 (E.D. Pa. 1982)).* Consistent with its findings above, the court finds that plaintiff has satisfied each element of its prima facie case.

Nonetheless, the court still must determine whether defendant's commercial speech enjoys First Amendment protection. Defendant contends that its statements are "inextricably intertwined" with protected political speech and, consequently, all of its communications are entitled to full First Amendment protection. Defendant relies heavily on the Supreme Court's decision in *Riley v. National Federation of the Blind, 487 U.S. 781, 101 L. Ed. 2d 669, 108 S. Ct. 2667 (1988).* In Riley, the Court assessed the constitutionality of a North Carolina statute [*45] which required solicitors of charitable contributions to divulge to potential donors the percentage of the previous year's donations that actually went to charities. In deciding that it would apply strict scrutiny analysis to the statute, the Court noted that "where, as here, the component parts of a single speech are inextricably intertwined, we cannot parcel out the speech, applying one [standard of review] test to one phrase and another test to another phrase." *Id. at 796.*

The Court revisited the issue of "inextricably intertwined" speech in Fox. See *492 U.S. 469, 109 S. Ct. 3028, 106 L. Ed. 2d 388.* In Fox, the Court reviewed the constitutionality of a state university regulation that prohibited private commercial enterprises in student dormitory rooms. The Court distinguished its holding in Riley by finding that the essentially commercial "Tupperware parties" involved in Fox did not enjoy full First Amendment immunity from state regulation -- even though the commercial activity at issue in Fox combined "sales pitches" with lectures on home economics, personal finance, and other protected forms of "pure" speech. Writing for the Court, Justice Scalia explained that in Riley,

> the [*46] commercial speech (if it was that) was "inextricably intertwined" because the state law required that it be included. By contrast, there is nothing whatever "inextricable" about the noncommercial aspects of these ["Tupperware"] presentations. No law of man or of nature makes it impossible to sell housewares without teaching home economics, or to teach home economics without selling housewares.

Fox, 492 U.S. at 474.

Defendant fails to appreciate the Supreme Court's distinction between the protected "inextricably intertwined" speech in Riley and the unprotected "voluntarily intertwined" speech in Fox. In the case at bar, defendant voluntarily interspersed its protected speech relating to heightened standards for warfarin

sodium drugs with comments about plaintiff's product, which comments are alleged to be false and misleading. Nothing required defendant to mislead consumers and disparage plaintiff's product while expressing its protected opinions on the standards governing warfarin sodium.

Thus, defendant's commercial speech is not "inextricably intertwined" with its protected speech. Because false and misleading commercial speech does not enjoy First Amendment [*47] protection, n14 defendant's statements are subject to Lanham Act scrutiny. Defendant's motion to dismiss plaintiff's Lanham Act claim is denied.

> n14 Commercial speech, when found to be false and misleading, "is not protected by the First Amendment at all." *City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 434, 123 L. Ed. 2d 99, 113 S. Ct. 1505* (Blackmun, J., concurring). Commercial speech enjoys "less protection . . . than . . . other constitutionally safeguarded forms of expression", *Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 64-65, 77 L. Ed. 2d 469, 103 S. Ct. 2875 (1983),* because "there is greater potential for deception or confusion in the context of certain advertising messages." *Id. at 65.* Moreover, commercial speech is marked by "greater objectivity and hardiness . . . [which] may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 771 n.24, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976).*

[*48]

C. Plaintiff's Robinson-Patman Claim

Section 2(c) of the Robinson-Patman Act reads, in relevant part:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant . . . anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods . . . either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c). Congress enacted this section in order to combat the use of "dummy" brokerage fees as a means of securing unlawful price rebates. The Supreme Court has found the language of § 2(c) applicable to commercial bribery. See *FTC v. Henry Broch & Co., 363 U.S. 166, 169 n.6, 4 L. Ed. 2d 1124, 80 S. Ct. 1158 (1960)* ("the debates on the bill show clearly that § 2(c) was intended to proscribe other practices such as the 'bribing' [*49] of a seller's broker by the buyer") (dictum). Commercial bribery is an aspect of "the classic arrangement that § 2(c) aimed to eliminate -- a situation where the fiduciary of one party is influenced by another party to the transaction by the payment of brokerage when no services are performed." *Yeager's Fuel, Inc. v. Pennsylvania Power & Light Co., 953 F. Supp. 617, 665 (E.D. Pa. 1997);* accord *Harris v. Duty Free Shoppers Ltd., 940 F.2d 1272, 1274 & n.3 (9th Cir. 1991).* With respect to commercial bribery, the Third Circuit has required the plaintiff to show that "the illegal payments in question crossed the line from buyer to seller or vice versa." See *Environmental Tectonics v. W.S. Kirkpatrick, Inc., 847 F.2d 1052, 1066 (3d Cir. 1988)* (citing *Seaboard Supply Co. v. Congoleum Corp., 770 F.2d 367, 372 (3d Cir. 1985)).*

Defendant argues that plaintiff has failed to allege that the financial incentives offered by defendant constituted unlawful bribes to fiduciaries of Coumadin purchasers. (D.I. 12; at 25-26 (98 Civ. 1695)) In its complaint, plaintiff alleges that defendant paid rebates and/or "administrative fees" to pharmacy benefit managers, managed care companies, [*50] retail pharmacies, and pharmacy wholesalers. (D.I. 1, PP 53, 56, 57, 59 (98 Civ. 1695)) Plaintiff explains that pharmacy benefit managers act as fiduciaries for managed care companies, insurance companies, and

others who employ them to broker cost-effective deals with pharmaceutical sellers. Plaintiff claims that these rebates and fees were designed to exclude its generic warfarin sodium from the anticoagulant market. (D.I. 1, at P 53 (98 Civ. 1695)) Plaintiff further alleges that these payments were not made in exchange for any services rendered in connection with the sale of Coumadin. (D.I. 1, PP 53, 58 (98 Civ. 1695))

At this stage of the proceedings plaintiff's complaint permits the inference that defendant unlawfully bribed these pharmacy benefit managers as well as the ultimate purchasers of Coumadin. Because these rebates were never offered by defendant until the introduction of generic warfarin sodium (D.I. 1, P 61 (98 Civ. 1695)), the court can also infer that these financial incentives were offered in order to exclude generic warfarin sodium from the oral anticoagulant market. As such, plaintiff has stated a claim of commercial bribery under § 2(c) of the Robinson-Patman [*51] Act.

D. Plaintiff's New York General Business Law Claims

Count V of the complaint alleges that defendant's false and misleading statements violated §§ 349 and 350 of the New York General Business Law. Section 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce." *N.Y. Gen. Bus. L. § 349* (McKinney 1997). Section 350 states that "false advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." Id. § 350. In an action brought under either section, the plaintiff must show "(i) that the act or practice was misleading in a material respect, and (ii) that the plaintiff was injured." *Coors Brewing Co. v. Anheuser-Busch Cos., 802 F. Supp. 965, 975 (S.D.N.Y. 1992).* Although the New York legislature enacted the statute as a consumer protection measure, see *Genesco Entertainment v. Koch, 593 F. Supp. 743, 751 (S.D.N.Y. 1984),* "corporate competitors now have standing to bring a claim under this [statute] . . . so long as some harm to the public at large is at issue." *Bristol-Myers Squibb Co. v. McNeill-P.P.C., Inc., 786 F. Supp. 182, 215* (E.D.N.Y.), [*52] vacated in part on other grounds, *973 F.2d 1033 (2d Cir. 1992).* "The critical question, then, is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor." *Securitron Magnalock Corp. v. Schnabolk, 65 F.3d 256, 264 (2d Cir. 1995).*

In its supporting brief, defendant reiterates its claim that its public statements enjoy First Amendment immunity and, therefore, cannot serve as grounds for liability under the New York General Business Law. (D.I. 12 at 28 n.9 (98 Civ. 1695)) Consistent with the findings above that at least some of defendant's speech is not protected by the First Amendment, the court further finds that plaintiff has alleged materially false and misleading statements by the defendant that harmed purchasers of anticoagulant drugs. Therefore, the plaintiff has stated a claim for relief under §§ 349 and 350 of the New York General Business Law. Defendant's motion to dismiss these claims is denied.

E. Plaintiff's New York Common Law Claims

In Count VI of its complaint, plaintiff alleges that defendant's false statements constituted common law trade disparagement. "Trade libel or product disparagement [*53] is an action to recover for words or conduct which tend to disparage or negatively reflect upon the condition, value or quality of a product or property." *Angio-Medical Corp. v. Eli Lilly & Co., 720 F. Supp. 269, 274 (S.D.N.Y. 1989).* In order to prove product disparagement the plaintiff must plead and prove "(1) falsity of the statement, (2) publication to a third person, (3) malice (express or implied), and (4) proven special damages." Id. New York courts have defined special damages as "the pecuniary loss resulting directly from the effect of a defendant's allegedly wrongful conduct." *Charles Atlas, Ltd. v. Time-Life Books, Inc., 570 F. Supp. 150, 155 (S.D.N.Y. 1983);* see also *Angio-Medical Corp., 720 F. Supp. at 274* (describing special damages as the "natural and immediate consequence of the disparaging statements"). Loss of sales is a proper item of special damages. See *Charles Atlas, Ltd., 570 F. Supp. at 155.*

In the case at bar, plaintiff sufficiently alleges that defendant's numerous public comments were malicious and that they disparaged the quality of plaintiff's generic warfarin sodium. Defendant argues that plaintiff has failed to properly plead special [*54] damages because plaintiff has not specified the particular customers with whom it would have done business but for defendant's disparaging statements. While defendant rightly notes that some New York courts have required such specificity, at least one New York court has recognized the need for a more liberal approach in cases where it is "virtually impossible to identify those who did not order

the plaintiff's product" because "such people would simply have failed to order, thus leaving no record of their identity." *Charles Atlas, Ltd., 570 F. Supp. at 156* (citing William Prosser, Handbook of the Law of Torts § 128, at 921-22 (4th ed. 1971); see also *Teilhaber Mfg. Co. v. Unarco Materials Storage, 791 P.2d 1164, 1167 (Colo. Ct. App. 1989).*

Plaintiff has not cited the specific customers it lost because of defendant's allegedly false and misleading statements. Plaintiff, however, has alleged that its market share in the oral anticoagulant market has suffered because of defendant's allegedly misleading publicity campaign. At this stage of the proceedings, the court finds that plaintiff has pled special damages with sufficient particularity. Given the mass dissemination of [*55] defendant's allegedly false and misleading statements, the court finds that demanding more specificity from plaintiff at this early stage in the litigation would be unfair and inappropriate.

Count VII of plaintiff's complaint alleges tortious interference with prospective business relations. In order to prevail on such a claim, "a plaintiff must demonstrate that the defendant interfered with business relations existing between a plaintiff and a third party, either with the purpose of harming the plaintiff or by means that are dishonest, unfair, or improper." *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council, 857 F.2d 55, 74 (2d Cir. 1988).* A cause of action for tortious interference with prospective business advantage "applies to those situations where the third party would have entered into or extended a contractual relationship with plaintiff but for the intentional and wrongful acts of the defendant." *M.J. & K. Co. v. Matthew Bender & Co., 220 A.D.2d 488, 631 N.Y.S.2d 938, 940 (N.Y. App. Div. 1995)* (quoting *WFB Telecomms., Inc. v. NYNEX Corp., 188 A.D.2d 257, 590 N.Y.S.2d 460, 461 (N.Y. App. Div. 1992)).*

In the present case, plaintiff alleges that, due to defendant's [*56] false and misleading statements, pharmacy benefit managers, managed care companies, and others refused to purchase plaintiff's generic warfarin. The facts reveal that these entities normally prefer less expensive generic drugs to branded pharmaceuticals. At this stage of the proceedings, plaintiff is entitled to the inference that, but for defendant's false and misleading statements, these third parties would have entered into contracts with plaintiff. Plaintiff has presented sufficient factual support to state a claim for relief under common law tortious interference with prospective business advantage. Defendant's motion to dismiss is denied.

VI. SUFFICIENCY OF CLASS PLAINTIFFS' COMPLAINTS

Class plaintiffs' antitrust complaints are identical: they seek treble damages and injunctive relief under §§ 4 and 16 of the Clayton Act for allegedly supracompetitive prices charged for Coumadin by defendant. Class plaintiffs' factual summaries of defendant's alleged violations of Sherman § 2 mirror plaintiff's complaint. The court will address class plaintiffs' antitrust claims as a whole. Class plaintiff Tischler also alleges that defendant's actions violate the Florida Deceptive [*57] and Unfair Trade Practices Act ("DUTPA"). *Fla. Stat. Ann. §§ 501.201* et seq. Class plaintiff Steckel additionally alleges several Pennsylvania state law claims.

A. Class Plaintiffs Lack Antitrust Standing

Class plaintiffs seek treble damages under § 4 of the Clayton Act n15 for the allegedly supracompetitive prices charged for Coumadin by defendant. Citing the Supreme Court's decision in *Illinois Brick Co. v. Illinois, 431 U.S. 720, 52 L. Ed. 2d 707, 97 S. Ct. 2061 (1977),* defendant argues that class plaintiffs lack antitrust standing because they are indirect purchasers of Coumadin. Class plaintiffs argue that the "bright-line" rule of Illinois Brick does not bar their claim because the Supreme Court has enunciated a broader antitrust standing test in *Associated General Contractors, Inc. v. California State Council of Carpenters, 459 U.S. 519, 74 L. Ed. 2d 723, 103 S. Ct. 897 (1983)* ("AGC"). The court finds that even under the more flexible balancing test of AGC, class plaintiffs still lack antitrust standing.

> n15 Section 4 of the Clayton Act provides, in pertinent part, that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court . . . and shall recover threefold the damages by him sustained. . . ." *15 U.S.C. § 15*(a).

[*58]

In AGC, the Supreme Court synthesized its previous rulings on antitrust standing by analyzing five factors to resolve the standing issue before it. As the Third Circuit explained in *McCarthy v. Recordex Serv., Inc., 80 F.3d 842, 850 (3d Cir. 1996)*, the Supreme Court considered (1) the causal connection between the antitrust violation and the harm to the plaintiff, (2) whether the antitrust injury is "of the type that the antitrust statute was intended to forestall," (3) the directness or indirectness of the asserted injury, (4) the existence of more direct victims of the alleged violation, and (5) the potential for duplicative recovery or complex apportionment of damages. See *id. at 850* (citing *AGC, 459 U.S. at 537-44)*.

These factors, when applied to the facts at bar, weigh heavily against class plaintiffs. Factors one and three require class plaintiffs to show that defendant's monopolization of the oral anticoagulant market directly caused their injuries. Although class plaintiffs assert that they were forced to pay supracompetitive prices, their ability to trace this effect to the alleged anticompetitive conduct traverses "several somewhat vaguely defined links." [*59] *AGC, 459 U.S. at 540.*

In their complaints, class plaintiffs assert that class members may be identified from records maintained by pharmacies, drugstores, and managed care companies. (D.I. 1, P 7 (C.A. 97-659)) This demonstrates that class plaintiffs purchased Coumadin from intermediaries rather than from defendant. Each of these organizations purchased their supplies of Coumadin from pharmaceutical wholesalers. (D.I. 8 at 11 (C.A. 97-659)) Class plaintiffs, then, are third in the distribution chain of Coumadin. Although class plaintiffs do not discuss third party payor arrangements, it is almost certain that most of the 1.8 million class members had some sort of health insurance. More often than not, third party payors actually "pay" for the cost of prescriptions while patients pay only a yearly premium (some of which might be subsidized by the patient's employer). Other third party payor arrangements reimburse patients for part or all of the price paid for the prescription.

In sum, this case presents a classic indirect purchaser scenario. It is unclear from the complaints whether class plaintiffs suffered any antitrust injury at all. Any injuries actually suffered by class [*60] plaintiffs are too remote to justify antitrust standing.

Turning to the fourth AGC factor, the remoteness of class plaintiffs' injuries also points to the existence of more direct victims of defendant's allegedly unlawful conduct. If defendant's monopolization of the oral anticoagulant market resulted in supracompetitive prices for Coumadin, the insurance companies and third party payor organizations most likely absorbed some or all of that overcharge. Those organizations, and not more remote victims like class plaintiffs, are the proper parties to bring suit to recover the overcharge.

The fifth factor of the AGC analysis concerns the potential for duplicative recovery or complex apportionment of damages. Allowing class plaintiffs to proceed in the present case would expose defendant to multiple recoveries in antitrust actions brought by those more directly injured by its conduct. Moreover, the sheer variety of third party payor plans would render the apportionment of damages among the class plaintiffs incredibly complex. A trier of fact would have to ascertain the percentage of the overcharge actually suffered by each class plaintiff. This figure would vary from plaintiff [*61] to plaintiff due to the involvement of third party payors and other intermediary purchasers -- some of which may or may not have absorbed the alleged overcharge. The apportionment problem is magnified by the fact that class plaintiffs purport to represent 1.8 million consumers of Coumadin.

The court concludes that class plaintiffs have not adequately alleged antitrust injury. As the Supreme Court has recognized, "an antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but 'despite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable.'" *Blue Shield of Va. v. McCready, 457 U.S. 465, 476-77, 73 L. Ed. 2d 149, 102 S. Ct. 2540 (1982)* (citing *Illinois Brick, 431 U.S. at 760* (Brennan, J., dissenting)). Class plaintiffs at bar lack antitrust standing, and defendant's motion to dismiss their Sherman § 2 claims is granted.

B. Injunctive Relief

Class plaintiffs seek injunctive relief from defendant's alleged monopolistic practices under § 16 of the Clayton Act. Section 16 provides, in relevant part, that "any person . . . shall be entitled to sue for and have injunctive relief . . . against [*62] threatened loss or damage by a violation of the antitrust laws. . . ." *15 U.S.C. § 26.* The Supreme Court has held that "in order to seek injunctive relief under § 16, a private plaintiff must

allege threatened loss or damage 'of the type the antitrust laws were designed to prevent and that flows from that which makes defendant['s] acts unlawful.'" *Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 113, 93 L. Ed. 2d 427, 107 S. Ct. 484 (1986)* (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489, 50 L. Ed. 2d 701, 97 S. Ct. 690 (1977)).* The Court remarked in Cargill that it would be "anomalous . . . to read the Clayton Act to authorize a private plaintiff to secure an injunction against a threatened injury for which he would not be entitled to compensation if the injury actually occurred." *479 U.S. at 112.* See also *West Penn Power Co., 147 F.3d at 264* (holding that "when seeking injunctive relief [under the Clayton Act], 'the complainant need only demonstrate a significant threat of injury from an impending violation of the antitrust laws.'") (emphasis added & citation omitted).

In the present case, class plaintiffs have not sufficiently alleged [*63] either antitrust injury or a causal connection between defendant's allegedly unlawful activity and their purported injury. Thus, class plaintiffs have failed to allege injury of the type the Sherman Act was designed to prevent. Therefore, class plaintiffs do not have standing to assert injunctive relief under § 16 of the Clayton Act.

C. Class Plaintiffs' State Law Claims

Because the court has dismissed class plaintiffs' federal claims, the only claims remaining arise out of state statutes and state common law. Pursuant to *28 U.S.C. § 1367*(c)(2)-(3), the court declines to exercise supplemental jurisdiction over these state claims because state law issues substantially predominate over the now dismissed federal claims. Therefore, the court grants defendant's motions to dismiss class plaintiffs' complaints.

VII. CONCLUSION

For the reasons stated, defendant's motion to dismiss plaintiff's claims is granted in part and denied in part. Defendant's motions to dismiss class plaintiffs' claims are granted. An order shall issue consistent with this memorandum opinion.

Not Reported in F.Supp.2d, 1999 WL 615164 (D.Del.)
(Cite as: Not Reported in F.Supp.2d)

E.I. Dupont De Nemours & Co. v. Millennium Chemicals, Inc.D.Del.,1999.Only the Westlaw citation is currently available.

United States District Court, D. Delaware.

E.I. DUPONT DE NEMOURS & CO., Plaintiff,

v.

MILLENNIUM CHEMICALS, INC. and Millennium Inorganic Chemicals, Inc ., Defendants.

No. C.A. 97-237-SLR.

Aug. 2, 1999.

Richard L. Horwitz, and Joanne Ceballos, of Potter, Anderson & Corroon LLP, Wilmington, Delaware, for Plaintiff, John C. Vassil, and Bruce D. DeRenzi, of Morgan & Finnegan, L.L.P., New York, New York, of counsel.

Jack B. Blumenfeld, of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware, for Defendants, David A. Kalow, and Kenneth L. Bressler, of Kalow, Springut & Bressler LLP, New York, New York, of counsel.

MEMORANDUM OPINION

ROBINSON, J.

I. INTRODUCTION

*1 Plaintiff E.I. DuPont De Nemours & Co. filed this patent infringement action against Millennium Chemicals, Inc. and Millennium Inorganic Chemicals, Inc. (collectively, "defendant") on May 1, 1997. Plaintiff is incorporated under the laws of Delaware and has its principal place of business in Wilmington, Delaware. (D.I.137, ¶ 2) Defendant is also a Delaware corporation with its principal places of business in Iselin, New Jersey and Hunt Valley, Maryland. (D.I.137, ¶¶ 3-4) The court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338. Venue is proper in this judicial district by virtue of 28 U.S.C. §§ 1391(c) and 1400(b).

Currently before the court is defendant's motion for summary judgment (D.I.92) and plaintiff's motion to dismiss, or in the alternative, to strike in whole or in part defendant's second and third counterclaims (D.I.168). In its motion, defendant argues that plaintiff's patents violate the definiteness requirement of 35 U.S.C. § 112 and therefore are invalid. For its part, plaintiff seeks dismissal of defendant's second and third counterclaims as untimely; in the alternative, plaintiff moves the court to strike all or part of defendant's counterclaims for failure to comply with the applicable statute of limitations. For the following reasons, the court shall deny both defendant's motion for summary judgment and plaintiff's motion to dismiss and grant in part plaintiff's motion to strike.

II. BACKGROUND

Plaintiff is the assignee of U.S. Patent Nos. 5,631,310 ("the '310 patent") and 5,889,090 ("the '090 patent").[FN1] These patents disclose processes for manufacturing "highly loaded" silanized titanium dioxide pigments in polyethylene or other polymer concentrates. Manufacturers use titanium dioxide pigment, which is white, to color various products, including plastics (such as trash bags and diaper linings), paints, and paper. This suit involves the use of these pigments in the plastic film market. (D.I.160, ¶ 49) There are three steps involved in coloring plastics using titanium dioxide pigment. First, the titanium dioxide pigment is coated with silanes or other materials. Second, the coated titanium dioxide pigment is shipped to a masterbatch, or concentrate, maker who forms the masterbatch by adding plastic to the pigment. Third, the masterbatch maker sells this concentrate to a plastic manufacturer who, in turn, adds more plastic to the concentrate and extrudes the pigmented plastic into film for use in various consumer products. (D .I. 93 at 4)

FN1. Initially, plaintiff alleged that defendant induced infringement of U.S. Patent No. 5,607,994 (the " '994 patent"), a product patent disclosing a "polyethylene matrix consisting essentially of polyethylene and about 50 to about 87% by weight silanized [titanium dioxide] pigment." (D.I. 93, Ex. A, '994 patent, col. 8, Ins. 20-23) After defendant filed the instant motion for summary judgment, plaintiff filed a second amended complaint (D.I.137), which substituted the '090 process patent for the '994 patent. Plaintiff appears to have abandoned suit over the '994 patent, focussing instead on defendant's alleged inducement of infringement of the '090 and '310 patents. Defendant's instant motion for summary judgment addresses only the '994 and '310 patents. Because the '994 patent is no longer the subject of suit, the court shall address only defendant's arguments touching on the '310 patent.

In the past, the use of titanium dioxide pigment in plastics had several processing disadvantages and often resulted in product quality problems. The processing disadvantages included poor dispersability of the pigment, high energy requirements for mixing the pigment, and low productivity. The pigment concentrate also occasionally produced "lacing" (holes or tears in the plastic film) and noxious gases or rendered the film resistant to printing. (D.I. 97 at 5) In response to consumer demand for less problematic pigmentation methods, both plaintiff and defendant developed "highly loaded" preparations of coated, silanized titanium dioxide pigment, which purportedly reduce the aforementioned processing and product quality disadvantages. In its second amended complaint, plaintiff alleges that defendant has induced infringement of the '310 and '090 patents through the manufacture, advertisement, promotion, and sale of silanized titanium dioxide pigment under the trade name "TiONA® RCL-188" (hereafter, "RCL-188") for use by masterbatch manufacturers in polyethylene concentrates. (D.I.137, ¶¶ 5-8)

III. DISCUSSION

A. Defendant's Motion for Summary Judgment

*2 Defendant argues that several terms used in the claims of the '310 patent are ambiguous and, therefore, are invalid for indefiniteness. Defendant points to the '310 patent's use of "coating," "mixture, " and "at least one" as examples of such indefiniteness. In interrogatories, defendant asked plaintiff to clarify the meaning of each of these disputed terms, but plaintiff refused "on the ground that it is premature in seeking the contentions of [plaintiff] during the initial phase of discovery." (D.I. 93, Ex. C at 2, 4, 5) The '310 patent employs these allegedly indefinite terms in the following manner.

1. "Coating"

The '310 patent uses "coating" as a verb to describe the process of coating the pigment with "at least one organosilicon compound." (D.I.93, Ex. B, col.8, Ins.24-25, 58) Defendant contends, without supporting evidence, that the ambiguity of "coating" lies in the fact that the chemical composition of the silane, if added to water, may change at the very least from (i) the time the ingredients are mixed to (ii) the time they attach to the pigment.

(D.I. 93 at 6) Due to this purported ambiguity, it is allegedly impossible to determine whether the '310 patent covers the formula for silane as it is added to water or the formula for silane as (or after) it coats the titanium dioxide pigment. (D.I. 93 at 7)

2. "Mixture"

Claim 3 of the '310 patent discloses a process for coating a titanium dioxide pigment with an organosilicon compound "comprising a mixture of .. . (a) at least one silane ... and (b) ... at least one polysiloxane...." (D.I. 93, Ex. B, col. 8, Ins. 59-60; col. 9, In. 5) Defendant asserts that the ambiguity lies in the patent's failure to claim the proportions of silane to polysiloxane which qualify as a mixture.

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(D.I. 93 at 7)

3. "At least one"

Finally, the '310 patent describes the pigment coating as comprising "at least one" silane or mixtures of "at least one" silane and "at least one" polysiloxane. (D.I. 93, Ex. B., col. 8, In. 24, 60; col. 9, In. 5) Defendant argues that this phrase is indefinite because the claims do not provide the meaning of, or the units of measurements associated with, the phrase "at least one." (D.I. 93 at 8)

On a motion for summary judgment, the movant bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). If a moving party fails to establish the absence of a genuine issue of fact, " 'summary judgment must be denied even if no opposing evidentiary matter is presented." ' *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 160 (1970) (quoting Advisory Committee Note on 1963 Amendment to Rule 56(e)).

*3 In the context of the instant motion, defendant must demonstrate that there is no genuine issue of material fact with respect to the indefiniteness of the '310 patent claims. A patent claim is indefinite and, therefore, invalid if the claims fail to "particularly point[ ] out and distinctly claim [ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. Although compliance with § 112 is a question of law, *see Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed.Cir.1986), it rests on a determination of " whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed.Cir.1993). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Id.* The degree of precision necessary to satisfy § 112 depends upon the subject matter and cannot be viewed in the abstract. *See id.; Shatterproof Glass Corp. v. Libbey-Owens Ford Co .*, 758 F.2d 613, 624 (Fed.Cir.1985).

At issue, then, is whether one skilled in the art would find the '310 patent's use of these disputed terms indefinite. Defendant, however, offers neither evidence of the requisite degree of skill in the art nor evidence of how one skilled in the art would interpret the disputed terms. Instead, defendant merely argues in rhetorical fashion that the aforementioned terms are indefinite. Defendant cannot prevail by arguing that these terms are indefinite to any reader of the patent; rather, defendant must demonstrate that those skilled in the art would find them indefinite. *See Miles Labs.*, 997 F.2d at 875. Terms that appear facially ambiguous to the lay reader may be perfectly definite to those versed in the technology at issue. *See, e.g., Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 821 (Fed.Cir.1988) (explaining that terms such as " closely approximate," "approach each other," and " substantially equal" are upheld by courts "when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention"); *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed.Cir.1984) (finding phrase "substantially equal to" sufficiently definite). On a motion for summary judgment, abstract and rhetorical arguments in support of indefiniteness simply do not satisfy defendant's burden of proof.

Defendant also argues that the court should infer indefiniteness from plaintiff's refusal, in its responses to defendant's interrogatories, to clarify the meaning of the disputed terms. Neither the law nor logic supports such an inferential leap. On a motion for summary judgment, the nonmoving party need not present opposing evidence of definiteness where, as here, the movant has failed to show the absence of genuine factual disputes. *See Adickes*, 398 U.S. at 160. Because defendant has failed to demonstrate the absence of genuine issues of material fact with respect to whether one skilled in the art would understand the disputed terms, the court shall deny defendant's motion for summary judgment.

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B. Plaintiff's Motion to Dismiss or, in the Alternative, to Strike

*4 Plaintiff moves the court, pursuant to Fed.R.Civ.P. 12(b)(6), to dismiss defendant's second and third counterclaims as untimely compulsory counterclaims filed without leave of court. In the alternative, plaintiff moves pursuant to Fed.R.Civ.P. 12(f) to strike defendant's second and third counterclaims as barred by the Delaware statute of limitations. (D.I.168) Defendant asserted these counterclaims in its May 14, 1999 answer to plaintiff's second amended complaint. (D.I.160) Defendant's second counterclaim alleges that plaintiff violated § 43(a) of the Lanham Act by making false and deceptive statements about defendant's RCL-188 product. (D .I. 160, ¶¶ 71-73) The third counterclaim asserts a state law unfair competition claim based on these same allegations. (D.I.160, ¶¶ 74-75)

1. Plaintiff's Motion to Dismiss

In support of its motion, plaintiff argues that defendant's second and third counterclaims are compulsory and, therefore, should have been asserted earlier than in its answer to plaintiff's second amended complaint. Plaintiff, however, offers no compelling justification for departing from the well established rule that a defendant may include counterclaims in its answer to an amended complaint. *See Standard Chlorine of Del., Inc. v. Sinibaldi,* Civ. A. No. 91-188-SLR, 1995 WL 562285, at *2 (D.Del. Aug. 24, 1995); *Joseph Bancroft & Sons Co. v. M. Lowenstein & Sons, Inc.,* 50 F.R.D. 415, 419 (D.Del.1970). Courts in this district have reasoned that, because the amended pleading relates back to the date of the original pleading, the amending pleader "can hardly be heard to complain that claims filed against him are improper because they should have been asserted in response to his original pleading." *Joseph Bancroft & Sons,* 50 F.R.D. at 419.

In the present case, plaintiff filed its second amended complaint on April 7, 1999. (D.I.137) In due course, defendant then filed its answer, which included the instant counterclaims. Under the settled law of this judicial district, defendant's counterclaims were filed in a timely manner. Thus, the court shall deny plaintiff's motion to dismiss.

2. Plaintiff's Motion to Strike

There remains, however, the issue of whether the relevant statute of limitations bars defendant from relying on some or all of the allegations asserted in support of its second and third counterclaims. The Lanham Act provides no statute of limitations. Generally, when a federal statute provides no statute of limitations federal courts look to the applicable state statute of limitations for guidance. *See Beauty Time, Inc. v. Vu Skin Sys., Inc.,* 118 F.3d 140, 143 (3d Cir.1997). Accordingly, the court must look to the Delaware statute of limitations for the relevant limitations period for both defendant's Lanham Act and state unfair competition counterclaims.

The Delaware statute of limitations provides that " no action based on a statute, and no action to recover damages caused by an injury unaccompanied with force ... shall be brought after the expiration of 3 years from the accruing of the cause of such action...." 10 Del. C. § 8106. Because defendant's second counterclaim is "an action based on a statute" and defendant's third counterclaim is " an action to recover damages caused by an injury unaccompanied by force," Delaware's three year statute of limitations applies in the absence of an equitable exception.

*5 Most of defendant's allegations fall within this three year period. Indeed, defendant asserts that plaintiff currently "is informing its customers and potential customers-all of whom are either customers or potential customers of [defendant]-that the use of [defendant's] RCL-188 product will infringe [plaintiff's] patents, even though [plaintiff] knows ... that its patents are invalid and unenforceable." (D.I.160, ¶ 63) Although defendant provides no specific dates for plaintiff's allegedly deceptive statements, defendant has asserted an ongoing pattern of misrepresentations and disparagement of its RCL-188 pigment by plaintiff. As such, these allegations fall within the limitations period.[FN2] Insofar as defendant relies

on plaintiff's false statements about defendant's RCL-188 product, the statute of limitations does not bar defendant's second and third counterclaims.

> FN2. Defendant need not, as plaintiff argues, specify the exact date of these alleged falsehoods.

Defendant, however, also refers to a July 1995 incident in support of its second and third counterclaims. Specifically, defendant alleges that in or about July 1995, [plaintiff] distributed to customers and potential customers a brochure comparing two of its titanium dioxide products to [defendant's competing product, RCL-4]. In that brochure, [plaintiff] intentionally made the false claims that its R-101 and R-104 products had significantly better vinyl tinting strength than RCL-4 and better dispersability than RCL-4. In fact, [plaintiff's] own internal testing documents show otherwise. The brochure also falsely claimed that [defendant's] RCL-4 product contained methyl stearate-a compound disfavored by customers-when, in fact, RCL-4 contains no methyl stearate.

(D.I.160, ¶ 65) Because defendant filed its counterclaims in May of 1999, events relating to this 1995 brochure fall outside the three year limitations period. In the absence of some equitable exception, defendant cannot rely upon this 1995 brochure to support its second and third counterclaims.

Defendant claims that the "time of discovery rule" provides such an exception. The "time of discovery rule" tolls the statute of limitations where "an inherently unknowable injury ... has been suffered by one blamelessly ignorant of the act or omission and injury complained of, and the harmful effect ... develops gradually over a period of time...." *Cavalier Group v. Strescon Indus., Inc.*, 782 F.Supp. 946, 951 (D.Del.1992) (internal quotations and citation omitted). The statute of limitations period is tolled until a person of ordinary intelligence and prudence would have had facts sufficient to put them on notice of an injury. *Id.* Defendant claims in its answering brief, but not in its counterclaims, that it was "blamelessly ignorant" of plaintiff's allegedly misleading brochure until discovery commenced in the present litigation. (D.I. 176 at 11)

The court finds that the "time of discovery" rule is not applicable to the instant case. A misleading product brochure is not an "inherently unknowable injury," especially when the brochure in question was distributed to "potential customers" in a highly competitive market. As such, defendant's counterclaims with respect to this 1995 incident are barred by the statute of limitations. Moreover, the 1995 brochure is irrelevant and immaterial to the issues at bar because it refers to completely different products than those allegedly covered by the '310 and '090 patents. Accordingly, pursuant to Fed.R.Civ.P. 12(f), the court shall strike ¶ 65 from defendant's second and third counterclaims.

IV. CONCLUSION

***6** For the aforementioned reasons, the court shall deny defendant's motion for summary judgment and plaintiff's motion to dismiss and grant in part and deny in part plaintiff's motion to strike. An appropriate order shall issue.

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END OF DOCUMENT

EXHIBIT H

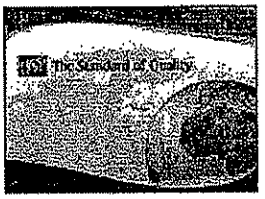
U.S. PHARMACOPEIA

About USP—An Overview

Who We Are

The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in more than 130 countries. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years.

What's New



Watch USP's new interactive overview
View an online presentation of USP's history and how our programs, products, and services can benefit you.

Resolutions define USP focus areas for 2005–2010.

USP is an independent, science-based public health organization. As a self-sustaining nonprofit organization, USP is funded through revenues from the sale of products and services that help to ensure good pharmaceutical care. USP's contributions to public health are enriched by the participation and oversight of volunteers representing pharmacy, medicine, and other healthcare professions as well as academia, government, the pharmaceutical industry, health plans, and consumer organizations.

Our Mission

USP promotes the public health by developing and disseminating quality standards and information for medicines, healthcare delivery, and related products and practices. Our standards and information help patients and practitioners maintain and improve health.

What We Do

Product Quality—Standards and Verification

USP establishes public standards to help assure good quality medicines, dietary supplements, and related products used to maintain health and treat disease. Prescription and over-the-counter medicines available in the United States must, by federal law, meet USP's public standards, where such standards exist. Many other countries require the use of high-quality standards such as USP's to assure the quality of medicines and related products. USP disseminates its standards to pharmaceutical manufacturers, pharmacists, and other users through its USP–NF and other publications, official USP Reference Standards materials, and Pharmacopeial Education courses.

USP also conducts verification programs for dietary supplement ingredients and products. These programs involve independent testing and review to verify ingredient and product integrity, purity, and potency for manufacturers who choose to participate.

Patient Safety

USP operates two programs to promote safer care of patients who take medications and stay in hospitals. The Medication Errors Reporting Program allows healthcare professionals to directly report medication errors to USP. MEDMARX®, an Internet-based medication error and adverse drug reaction reporting program, is designed for use in hospitals and health systems. USP also uses its knowledge base to provide information that supports the healthcare community in the research and development of patient safety initiatives.

Healthcare Information

USP develops authoritative, unbiased information relating to various aspects of drug use and disseminates this information to practitioners, pharmacists, and others who make decisions about healthcare around the world. Significant among USP's healthcare information initiatives is the

development of a drug classification system that Medicare Prescription Drug Benefit plans may use to develop their formularies. USP also partners with the U.S. Agency for International Development in worldwide projects that help to assure drug quality and proper drug use in many developing countries.

ETSI - European Telecommunications Standards Institute - Printable and Accessible Text Files

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Read also: ETSI's Organizational Structure

Who is ETSI?

The European Telecommunications Standards Institute (ETSI) is an independent, non-profit organization, whose mission is to produce telecommunications standards for today and for the future.

Based in Sophia Antipolis (France), the European Telecommunications Standards Institute (ETSI) is officially responsible for standardization of **Information and Communication Technologies (ICT)** within Europe. These technologies include telecommunications, broadcasting and related areas such as intelligent transportation and medical electronics.

ETSI unites **655 members from 59 countries** inside and outside Europe, including manufacturers, network operators, administrations, service providers, research bodies and users - in fact, all the key players in the ICT arena.

ETSI plays a major role in developing a wide range of standards and other technical documentation as Europe's contribution to world-wide ICT standardization. This activity is supplemented by interoperability testing services and other specialisms. ETSI's prime objective is to support global harmonization by providing a forum in which all the key players can contribute actively. ETSI is officially recognized by the European Commission and the EFTA secretariat.

ETSI's Members determine the Institute's work programme, allocate resources and approve its deliverables. As a result, ETSI's activities are closely aligned with market needs and there is wide acceptance of its products.

ETSI's standards are built on consensus.

Standardization in a changing world

The Information Society offers huge potential to enrich everyone's lives. We can communicate with the other side of the world almost as easily as we speak to our next-door neighbour. Our children take for granted what their PC or mobile phone will do. New technology is affecting our work, our rest and our play.

But with new opportunities come challenges. Technology makes things quicker, easier, better. But it is also more complex.
Achieving the Information Society involves practical action by a wide range of players. Data exchange around the world, using different platforms, with different practices, different languages and character sets, requires a neutral tool for all parties to communicate.

Standardization carves a path through this complexity.

The Benefits of Standardization

Standardization:

- enable interoperability
- encourages innovation, fosters enterprise and opens up new markets
- creates trust and confidence in products
- expands the market, brings down costs and increases competition
- helps prevent the duplication of effort

Standardization is an essential requirement for the open exchange of information; without it, the network simply will not work.

There are two major caveats, however, without which standardization could impede rather than accelerate progress:

- standards must be produced at a speed that is consistent with market demand,
- standards must consider all interested parties, or they will not be widely acceptable.

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